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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:
A61M 27/00, A61F 9/00	A1	WO 91/12046
		(43) International Publication Date: 22 August 1991 (22.08.91)

(21) International Application Number: PCT/SE91/00097

(22) International Filing Date: 12 February 1991 (12.02.91)

(30) Priority data:
9000491-2 12 February 1990 (12.02.90) SE

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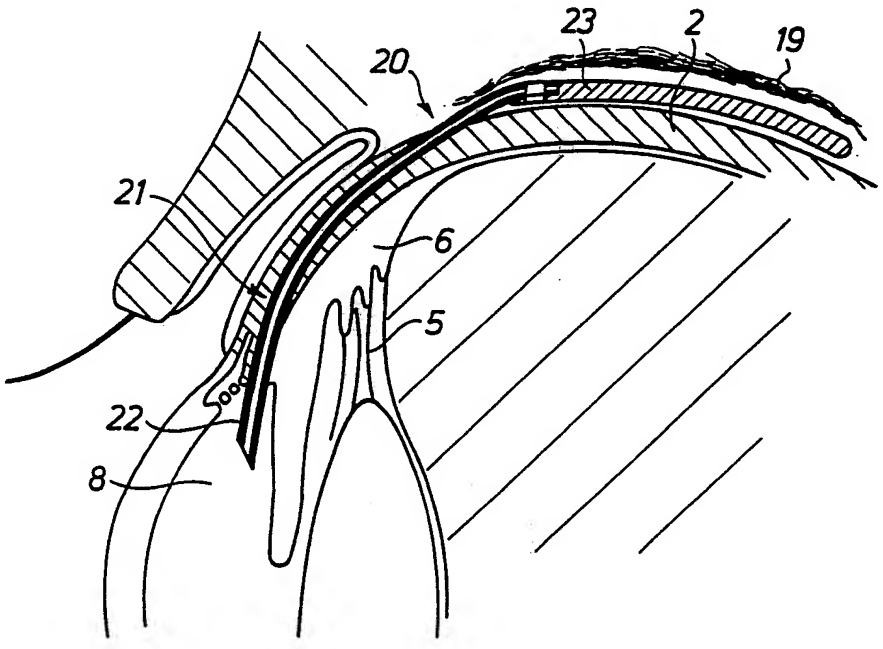
(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: GLAUCOMA VALVE



(57) Abstract

The invention relates to a glaucoma valve, comprising an elongated tube (22) and a curved plate (23) attached to one end of said tube (22) for connecting the interior of the eye to surrounding tissue and draining a liquid flow from the interior of the eye to said surrounding tissue. A channel enclosed in said tube and said plate is formed with a section having a closed interior envelope surface, the inner diameter and the length of said section being adjusted to accomplish the desired restriction of said liquid flow.

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GLAUCOMA VALVE

The invention relates to a glaucoma valve, comprising an elongated tube and a curved plate attached to one end of the tube for connecting the interior of the eye to the surrounding tissue and draining a fluid from the interior of the eye to the surrounding tissue.

Glaucoma is an eye disease which, if not treated, gradually leads to loss of vision. The loss of vision is caused by the death and disappearance of the nerve fibers located in the optical nerve and which normally transmit the information of vision from the retina of the eye to the visual cortex in the brain. The loss of the optical nerve fibers in connection with glaucoma is in turn caused by an abnormally high intraocular pressure in the eye.

In the interior of the eye there is constantly produced the so called aqueous humor, a clear liquid mainly consisting of water. The aqueus humor, which is produced in the ciliary body of the eye behind the iris, flows through the pupill towards the so called anterior chamber of the eye where the aqueous humor leaves the eye partly via a drainage system consisting of a number of fine pores, called the trabecular meshwork, partly via Schlemm's channel as well as the aqueous veins. In a normal eye there exists a balance between the production of aqueous humor and the outflow through the drainage system that causes the hydrostatic pressure to reach a sufficiently high level in order to expand the tissues of the eye without injuring them. In connection with glaucoma this balance has been disturbed, usually caused by a too high flow resistance through the trabecular meshwork increasing whereby the pressure in the eye.

The treatment of glaucoma aims to lower the pressure of the liquid in the eye to a normal level. This can often be accomplished by means of different types of medication.

In several cases, however, medication only is not sufficient and a hole is then made through which aqueous humor can leak from the eye. Thus, there is accomplished an artificial drainage with a lowering of the fluid pressure of the eye as a consequense. The hole in the wall of the eye which is accomplished by surgery unfortunately often fills up again increasing the pressure. In order to secure a permanent drainage of aqueous humor from the eye some kind of valve or drainage tube is sometimes used which is inserted (implanted) into the eye by operation. The drainage devices which are commercially available today have som disadvantages which are the cause of their rather limited use.

Usually these drainage devices or so called glaucoma valves consist of a thin tube which is placed with one end in the anterior chamber and the other end on the surface of the sclerotic layer under what is called Tenon's capsule far up under the upper eyelid. At the upper end of the tube is often a plate or a so called sealant connected which is made of some plastic material. The purpose of the plate is to increase the liquid absorbing surface where the outflowing aqueous humor meats the tissues on the outside of the eye. In some cases some kind of pressure regulating valve device is connected to the upper end of the tube in order to accomplish a certain low back pressure in the tube thus preventing the pressure level in the eye from falling to zero.

Glaucoma valves available today exhibit among other things the following drawbacks:

During one or some weeks after the implantation the flow of aqueous humor often becomes to heavy and the pressure in the eye to low. This results in the bulging of the lense and the iris of the eye towards the back of the cornea and thereby the damaging of both the lense and the cornea. Furthermore, the too low pressure in the eye can

cause the loosening of the choroid coat as it is called at the back of the eye with visual impairement as a consequense.

Some weeks after the operation a fibrous scar tissue is often formed around the upper end of the tube and around the plate and this scar tissue then causes a hindering effect on the flow of aqueous humor partly increasing the pressure in the eye . The liquid space between the lense/iris and the choroid coat is then regenerated and the loosening of the choroid coat usually abates. When this happens, however, permanent damages to the eye may already have appeared, which are caused by the initially too low pressure.

The scar tissue which is always formed around the upper end of the drainage tube and around the plate is in many cases so dense that it causes a too high flow resistance for the aqueous humor flowing out at the upper mouth of the tube. The intended lowering of the pressure in the eye is then not sufficient. In order to meet this problem the liquid absorbing surface can be increased either by a larger surface of the implant or by a later implantation of an additional valve. However, in both these cases the operating trauma increases more than if only one opertion and a smaller implant would have been enough.

The tubes of the now commercially available glaucoma valves have an outer diameter which is comparatively large and they are also comparatively stiff so as to facilitate the implantation. Usually the tube is implanted in such a way that it will for a certain distance run inside the sclerotic layer between its lamellas. If the tube is thick it will exert pressure on the tissue and thereby cause the gradual disapperance of sclerotic tissue. This sometimes results in the tube lying exposed on the surface of the eye. This is a very serious condition that calls for an im-

mediate operative measure in order to prevent a serious damage to the eye by the leakage of aqueous humor at the side of the tube or by the spreading of bacteria to the interior of the eye with a serious infection as a consequense.

One object of the present invention is to essentially overcome the above described problem with a glaucoma valve which in addition is very simple in its construction.

An other object of the invention is to provide a glaucoma valve which by its shape is easy to implant and with which the implantation implies a low risk of damage. After the implantation the risk of inflammation, rejection or other damages shall also be low.

In order to achieve the above mentioned objects the glaucoma valve according to the invention has obtained the characterizing features of claim 1.

The invention will now be further explained in more detail below by means of two embodiments reference being made to the accompanying drawings, in which

FIG. 1a is a cross sectional view of a healthy eye,

FIG. 1b is a cross sectional view of a part of a helthy eye in an enlarged scale,

FIG. 2 is a cross sectional view of an eye with an implanted valve according to the invention,

FIG. 3 is a side view of a part of a valve according to the invention,

FIG. 4 is a plan view from above of a part of a valve according to the invention,

FIG. 5 is a longitudinal section view of a tube according to the invention, and

FIG. 6 is a cross sectional view taken along a line A-A of the tube of FIG. 5.

FIG. 1a and 1b show a helthy eye. The eye consists of an almost spherical capsule with the cornea 1 in its front and the sclerotic layer 2 in its back. Both the cornea and

the sclerotic layer are built up by rather solid tissues which are expanded by the liquid pressure from the interior of the eye. In this way the eye keeps its shape. A short distance behind the cornea is the iris 3 located and behind this the lense 4. The latter is kept in place by very thin fibers, the zonule of Zinn 5, in the ciliary body 6. The musculature in the ciliary body can influence the tension in the zonula fibers and thus the shape of the lense. This is the cause of the adjustment of the eye for short distances (accomodation) which takes place with younger and middle aged individuals at work close to an object. The ciliary body also has another function, that is to produce the aqueous humor, as it is called, which occurs in special cells on the surface of the ciliary body (in the so called ciliary epithelium). The produced aqueous humor moves forward, bypass the lense and out through the pupil 7 to the anterior chamber 8 which is the liquid containing space situated between the back surface of the cornea and the front surfaces of the iris/lense. The aqueous humor leaves the anterior chamber of the eye via several very fine pores, jointly designated the trabecular meshwork 9, FIG. 1b. These pores are arranged along a circular band circumferentially located in the surface layer of the back of the cornea. When the aqueuos humor has passed the trabecular meshwork it reaches a circular channel, Schlemm's channel 10 in the periphery of the cornea and from there passes on via the aqueous veins 11, as they are called, out into the general blood circulation.

Behind the lense of the eye lies the vitreous body 12, a clear jelly like liquid. Between the vitreous body and the sclerotic layer lies the retina 13 and the choroid coat 14. From the retina emanate those nerve fibers which jointly form the optical nerve 15 and which transmit visual information from the eye to the brain. Within the front

part of the eye the sclerotic layer is covered by a relatively thin, loosely constructed opaque film, what is called conjuctiva 16. The conjuctiva does not cover the sclerotic layer on the back of the eye but curves forward at 17 and instead covers the inside 18 of the eyelid. From the area where the conjuctiva "turns" (at 17), and backwards, the surface of the sclerotic layer is covered by a loose, fibrous capsule of connective tissue, called Tenon's capsule 19.

The most usual form of glaucoma is when the fine pores in the trabecular meshwork is totally or partly clogged leading to an increase of the pressure in the eye and the damage of the optical nerve.

With reference to FIG. 2 the implantation of the device according to the invention, a glaucoma valve, will now be further described. From an incision in the surface of the sclerotic layer, at 20, a channel 21 is prepared within the sclerotic connective tissue opening into the anterior chamber 8 of the eye. Into the channel is introduced a fine tube 22, one end thereof opening in the chamber of the eye. The other end of the tube is connected to a plate 23 which in the embodiment shown is constructed of PMMA and in which the tube ends. The plate will lie on the surface of the eye (the sclerotic layer 2) under Tenon's capsule 19. The plate increases the liquid absorbing surface of the surrounding tissue where the aqueous humor flows out at the upper end of the tube.

From FIG. 3 and 4 the design of the plate 23 is more clearly evident. In the shown embodiment the plate is circular, slightly vaulted and constructed of PMMA. Other embodiments and materials are, however, also possible. For example both the tube and the plate can be constructed of the same material (silicon rubber) and then in one piece.

The plate is preferrably heparinized and coated with a layer of titanium. The thickness of the titanium layer should lay within the interval 200-1000 Å ($200*10^{-10}$m-$1000*^{-10}$m). The purpose of the surface coating with heparin or titanium is too drastically reduce the tissue reaction around the plate always arising from implantation of foreign material on the surface of the eye and which causes scar formation and thus detoriated absorption of the aqueous humor. By this measure a sufficient amount of aqueous humor flow is secured without the necessity of such a large surface of the plate.

One feature of the tube is that its inner diameter is less than that of prior art glaucoma valves. In a preferred embodiment the inner diameter is only 0.20 mm. Preferrably the inner diameter should lie within the interval 0.15-0.21 mm and the inner diameter should not exceed 0.25 mm. By the choice of inner diameter in this interval an effective drainage of aqueous humor is ensured without the risk of a too high flow with a too large pressure drop in the chamber of the eye as a consequense. The length of the glaucoma valve according to the invention will lie within the interval 15-20 mm. Together with the chosen inner diameter this length results in a desired restriction effect of the valve. If another length is chosen the inner diameter is adapted in order to keep the desired contracting effect. At a length of 10 mm a suitable inner diameter is about 0.18 mm. The restriction effect is available immediately after the implantation. According to the invention only a part of the tube has to be constructed with the above specified dimensions in order to obtain the desired restriction effect. This part of the tube, at least, has a closed interior envelope surface so that no abduction of aqueous humor will occur there. The remaining parts of the tube are constructed with greater dimensions in order not to contribute to

the restriction. The desired restriction effect corresponds to a counter pressure for the flow of aqueous humor of between 1 mm Hg and 15 mm Hg. At a high counter pressure from the tissue which surrounds the plate 23 the counter pressure in that part should be lower.

In an alternative, not shown, embodiment of the invention the plate 23 is constructed with an inner channel which in one end recieves the tube and the other end ends in the surface of the plate, for example in the center of the plate. The channel comprises a part with the above mentioned dimensions achieving the desired restricting effect. In one embodiment the channel is spiral shaped and ends in the center of the plate and in another alternative embodiment the channel is constructed as a coil of desired length with several parts running parallell.

An additional feature of the tube is that the lower end is bevelled. The tube is implanted with the lower bevelled edge positioned so that the opening will point obliquely ahead downwards towards the center of the cornea. This will eliminate the risk of obstructing the lower opening of the tube by the iris, if this should contact the lower end of the tube.

From FIG.6 which is a cross section along the line A-A of FIG. 5, another feature of the tube is shown. Since the cross section of the tube is elliptic several important characteristics are obtained. The sclerotic layer is constructed of several thin lamella which are arranged in parallell both between themselves and relative to the surface of the sclerotic layer. The individual lamella have comparatively high strength but are loosely connected with each other. This construction of the sclerotic layer results in an always flat cross section of the channel prepared for implantation.

An elliptic tube according to the invention adheres thoroughly against the channel in the sclerotic layer in order to obtain a good sealing between the tube and the channel. Thereby the risk of leakage of aqueous humor along the tube is reduced. A leakage at the side of the tube results in an uncontrolled outflow of aqueous humor and thus a too low pressure in the eye with the risk of permanent damages to the eye as a consequense.

An additional advantage of a tube elliptic in cross section is that the tube becomes more rigid compared with a tube circular in cross section and is thus more easier to introduce in the channel prepared.

A good sealing between the tube and the sclerotic layer can also be achieved with a circular tube but in order to obtain a good sealing the tube will then excert a comparatively high pressure towards the outer and inner surfaces of the sclerotic layer. The increased mechanical pressure which is excerted by a circular tube on the sclerotic tissue leads to a gradual breakdown of the tissue. The result is that until now available circular tubes of glaucoma valves sometimes are forced up and remain naked on the front surface of the eye. This risk is considerably lesser with a tube according to the invention. The risk of irritating the surrounding tissue is also considerably reduced both in connection with the implantation and afterwards during the life span of the implantate. The inside contoure of the tube is circular in the embodiment shown but this shape can be varied within the scope of the invention.

The very simple construction of the glaucoma valve results in a very long working life of the valve but a very small risk of complications.

CLAIMS

1. Glaucoma valve, comprising an elongated tube (22) and a curved plate (23) attached to one end of said tube (22) for connecting the interior of the eye to surrounding tissue and draining a liquid flow from the interior of the eye to said surrounding tissue, c h a r a c t e r i z e d by a channel enclosed in said tube (22) and said plate (23), said channel including a section having a closed interior envelope surface, said inner diameter and said length of said section being adjusted to accomplish the desired restriction of said liquid flow.

2. Glaucoma valve as in claim 1, c h a r a c t e r i z e d by said inner diameter of said section being less than or equal to 0.25 mm and said length of said section being chosen in order to obtain a counter pressure between 1 mm Hg and 15 mm Hg.

3. Glaucoma valve as in claim 1, c h a r a c t e r i z e d by said inner diameter of said section being within the interval 0.15-0.21 mm and said length of said section being chosen in order to obtain a counter pressure between 1 mm Hg and 15 mm Hg.

4. Glaucoma valve as in claim 1, c h a r a c t e r i z e d by said inner diameter of said section being 0.20 mm and said length of said section being chosen in order to obtain a counter pressure between 1 mm Hg and 15 mm Hg.

5. Glaucoma valve as in any preceeding claim c h a r a c t e r i z e d by said section being constructed as a channel in said plate (23).

6. Glaucoma valve as in any preceeding claim c h a r a c t e r i s e d by said tube (22) being constructed elliptical in cross section.

7. Glaucoma valve as in any preceeding claim c h a r a c t e r i z e d by the free end of said tube (22) being bevelled.

8. Glacoma valve as in any preceeding claim c h a r a c - t e r i z e d by said plate (23) being heparinized.

9. Glaucoma valve as in any of claims 1-7, c h a r a c - t e r i z e d by said plate (23) being coated with a titanium layer.

10. Glaucoma valve as in any of claims 1-7, c h a r a c - t e r i z e d by said plate (21) being made of titanium.

11. Glaucoma valve as in any of claims 1-7, c h a r a c - t e r i z e d by said plate (23) being made of silicon and constructed in one piece with said tube (22).

12. Glaucoma valve as in any of claims 1-7, c h a r a c - t e r i z e d by said plate being made of a rigid polymer material and connected with said tube (22).

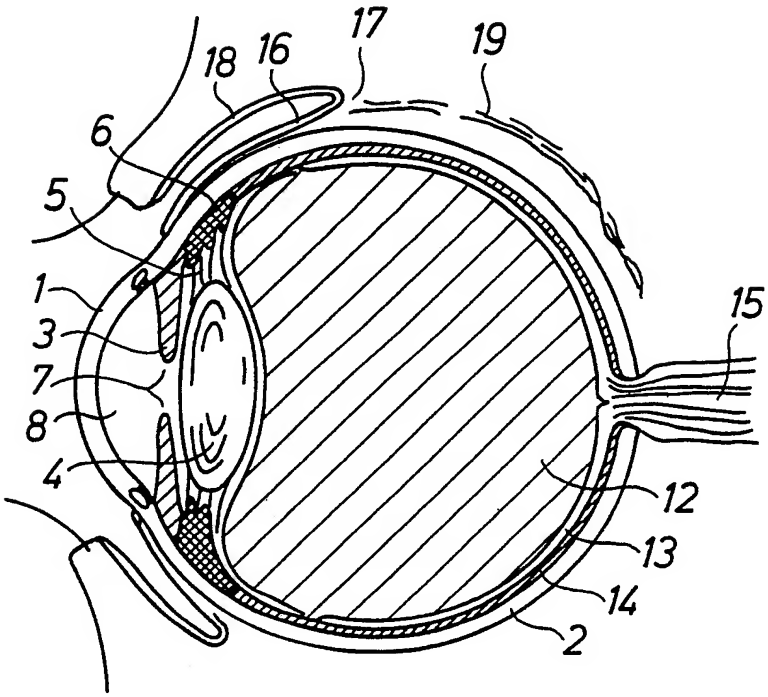

FIG. 1a

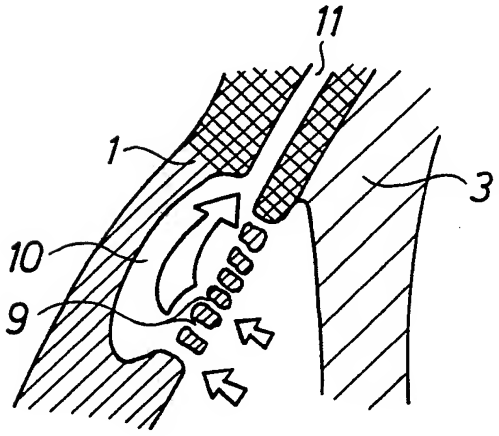

FIG. 1b

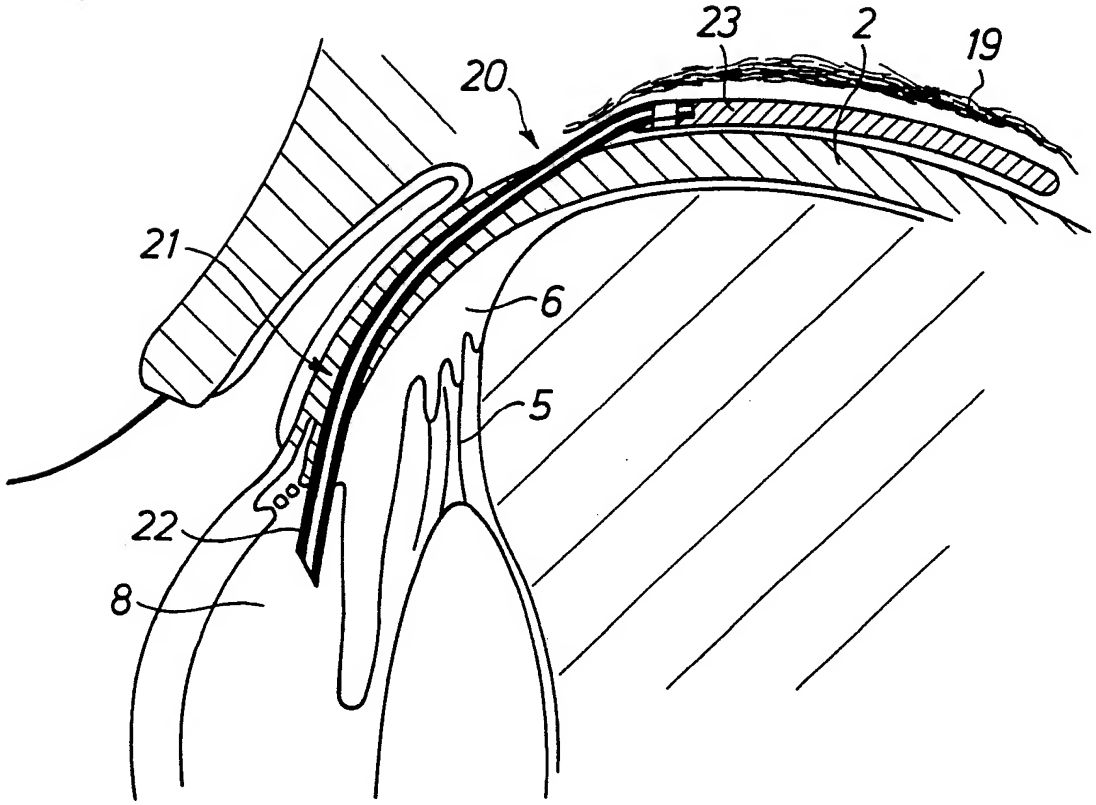

FIG. 2

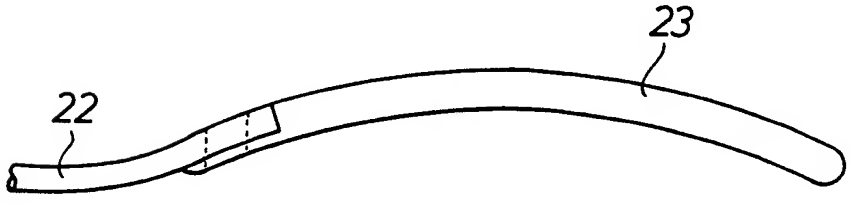

FIG. 3

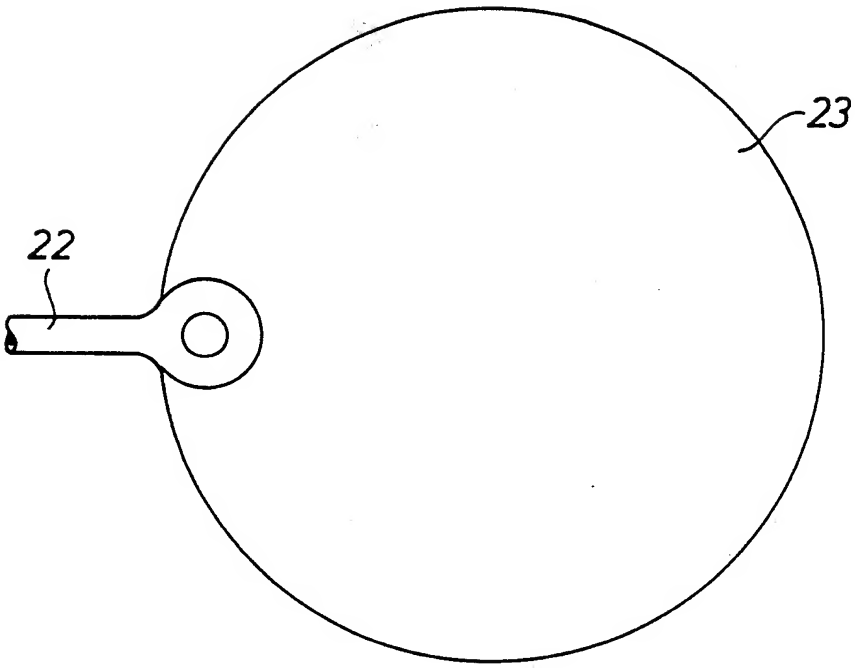

FIG. 4

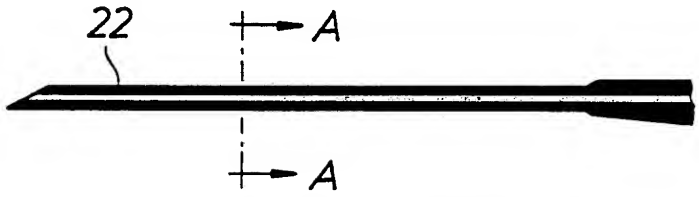

FIG. 5

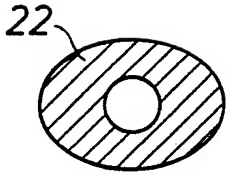

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 91/00097

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 M 27/00, A 61 F 9/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
IPC5	A 61 F; A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched[8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	US, A, 4750901 (MOLTENO) 14 June 1988, see the whole document --	1,8-12
Y	US, A, 3159161 (R.A. NESS) 1 December 1964, see the whole document --	1-8, 11
Y	US, A, 4826478 (SCHOCKET) 2 May 1989, see column 5, line 53 - line 56; column 7, line 30 - line 40; column 8	1-4
Y		7
Y	--	8
A	GB, A, 2172203 (THE VICTORIA UNIVERSITY OF MANCHESTER) 17 September 1986, see the whole document --	6

* Special categories of cited documents: [10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16th April 1991	1991 -04- 29
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	Magnus Thorén

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US, A, 4886488 (WHITE) 12 December 1989, see column 3, line 40 - line 58 --	9-12
A	US, A, 4787885 (BINDER) 29 November 1988, see the whole document --	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.PCT/SE 91/00097

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the Swedish Patent Office EDP file on 91-03-23
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US-A- 3159161	64-12-01	NONE	
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